## MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY SECRETARIAT OF ANIMAL AND PLANT HEALTH

## NORMATIVE INSTRUCTION 35, DATED SEPTEMBER 25, 2018

## MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY

## SECRETARIAT OF ANIMAL AND PLANT HEALTH

DOU dated 27/09/2018 (nº 187, Section 1, page 8)

THE SECRETARY OF ANIMAL AND PLANT HEALTH OF THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, using the powers conferred upon him by Articles 18 and 53 of Appendix I of Decree 8,852, of September 20, 2016, and pursuant to Law 1,283, of December 18, 1950, Decree 9,013, of March 29, 2017, and Case File no. 21000.033637/2018-90, resolves that:

Article 1. This Normative Instruction approves the procedures for recognition of health inspection systems and eligibility of foreign establishments by the Department of Inspection of Animal Products of the Secretariat of Animal and Plant Health of the Ministry of Agriculture, Livestock and Food Supply - DIPOA/SDA/MAPA.

Article 2. Those countries or part of their territories that are free of diseases that are harmful to national animal health security, and that wish to export animal products to Brazil are subject to the following, according to the provisions in the specific Brazilian legislation:

- I the recognition of equivalence of their sanitary inspection systems;
- II eligibility of the interested establishments; and
- III registration of animal products at DIPOA.

Article 3. For the recognition of equivalence as per item I of Article 2, the competent authorities of the countries interested in exporting animal products to Brazil must answer the technical questionnaires provided by DIPOA, regarding their competence, attributes, activities and methodologies for veterinary inspection, as well as the corresponding sanitary legislations and regulations.

Sole paragraph. The technical questionnaires will be prepared by the competent technical departments of the Secretariat of Animal and Plant Health (SDA), comprising animal health and inspection of animal products and, when necessary, livestock inputs, laboratories and residues and contaminants.

Article 4. A country interested in exporting to Brazil shall make a formal request by means of official diplomatic channels, with information about the products and categories of products of animal origin that it intends to export to Brazil, including the animal species, technological processing and list of manufacturing establishments.

Sole paragraph. The categories of animal products must be provided, based on the technological processes which the products undergo and their relationship with the treatments to mitigate risks for animal health or public health.

Article 5. A request for recognition of equivalence of the health inspection system will be initially assessed by the Department of Animal Health of the Secretariat of Animal and Plant Health of the Ministry of Agriculture, Livestock and Food Supply - DSA/SDA/MAPA to identify any hindrances or technical restrictions regarding animal health and the definition of the applicable health requirements.

Article 6. There being a favorable assessment by the DSA, the requests for recognition should be subjected to analysis by DIPOA and, whenever necessary, by other competent departments in the SDA.

Article 7. DIPOA will evaluate the information in the questionnaires submitted by the countries interested in exporting animal products to Brazil, with the objective of verifying the equivalence with the Brazilian veterinary inspection service.

Article 8. Once the information is considered equivalent, DIPOA will send a veterinary mission to check the inspection system and visit the establishments.

Sole paragraph. At the discretion of DIPOA, a prior visit to assess foreign establishments interested in exporting animal products of low public and animal health risk to Brazil may be waived, if the result of the analysis of the technical guestionnaires is favorable.

Article 9. As a result of the negotiations or bilateral agreements with the country, and at the discretion of DIPOA, supplementary procedures for the eligibility of new foreign establishments or the inclusion of new categories of products can be defined, establishing the mandatory filling out and sending of an individual questionnaire by the establishments, and the deadlines for the expiry of the eligibilities will also be defined.

Article 10. The eligibility of a foreign establishment will be granted as follows:

- I plant-by-plant eligibility is a modality that demands a mandatory visit to each plant in order to assess each establishment interested in exporting animal products to Brazil by DIPOA; or
- II Eligibility based on referral by the foreign health authority, in which the eligibility of new establishments or the adding of new categories of products may be performed by an appointment by the health authority of the foreign country and later certified by DIPOA, and a prior visit to the candidate establishment may be waived.
- Article 11. A country whose health inspection system has been recognized as equivalent to the Brazilian system for a certain area or animal species may require the extension of the recognition to other areas or animal species, and, to that end, it must supplement the information in the questionnaire mentioned in Article 3 about the production chain to be included.
- Paragraph 1. If the document-based check to extend the recognition of the health inspection system is favorable, DIPOA may dispense with the mission to the country for a temporary grant of extension of equivalence, and the on-site assessment will be adjourned to the next mission.
- Paragraph 2. The mission mentioned in Paragraph 1 above will only be waived when the activities for the inspection of animal products in the new areas or animal species are performed by the same competent agency or institution of the country of origin already recognized as equivalent to the Brazilian one.
- Article 12. A preliminary draft report of the foreign missions will be written within 60 (sixty) days of the end of the mission, and will be made available by the competent health authority in the foreign country for comments and proposed action plans in order to comply with the recommendations for the same period of time

Sole paragraph. After analyzing the comments and actions proposed by the foreign country, the final mission report will be drafted within 30 days, and should be published by DIPOA on MAPA's website.

- Article 13. Based on the negotiations or bilateral agreements with the foreign country, and at the discretion of SDA, the Brazilian veterinary missions may be paid for, totally or partially, by the country that intends to export animal products to Brazil.
- Article 14. Establishments interested in exporting animal products to Brazil must comply with the requirements in the specific Brazilian legislation and regulations regarding:
- I the conditions of the physical facilities, equipment, operational flowchart and industrial sanitation;
- II formulation, technological processes, packing and labeling of animal products;
- III application of good manufacturing practices, and methodologies that guarantee food safety based on the principles of the Hazard Analysis and Critical Control Points (HACCP); and
- IV Animal welfare.

Article 15. After the evaluation procedures set forth in this Normative Instruction are completed, and if the report is favorable to the equivalence with the Brazilian health inspection system, DIPOA will issue a declaration of recognition of the country as fit to export animal products to Brazil.

Sole paragraph. In the declaration of recognition of equivalence, there will be information about the animal products or categories of animal products authorized per areas or animal species, the modality of eligibility for new establishments or inclusion of products and additional established requirements.

Article 16. The templates of the International Health Certificates for Importation must be communicated by DIPOA to be acknowledged and verified at the points of entry and reinspection of the competent departments.

Article 17. DIPOA will update the list of countries, establishments and categories of animal products authorized for export to Brazil, and publish it on MAPA's website.

Sole paragraph. The list of authorized products will follow the criteria for the categories mentioned in Article 4.

Article 18. SDA, supported by DSA, can, at any moment, suspend, totally or partially, the importation of animal products from countries affected by diseases that represent an animal health risk.

Article 19 - DIPOA will perform periodical audits on the countries with recognized equivalence and on the eligible establishments in order to ensure the maintenance of the appropriate conditions, and DIPOA can suspend, totally or partially, at any time, the approval of the countries or the eligibility of the establishments, in the following cases:

I - the health inspection system is compromised; or

II - the hygiene and sanitary standard of the establishments and their respective products are compromised.

Article 20. DIPOA may suspend, totally or partially, the approval of the countries or eligibility of the establishments, in the following cases:

I - if violations to the Brazilian legislation are detected on the reinspection of imported animal products;

II - when the health authority of the country of origin fails to comply with and inform Brazil about the corrective and preventive actions taken for the detected violations; or

III - when the health authority of the country of origin fails to produce the information requested by Brazil.

Article 21. If severe irregularities that pose a risk to public health or constant repetitions occur, the Director of DIPOA may decide to exclude all foreign establishments in this area or even from the entire country.

Article 22. The sanitary authority of the foreign country that has the sanitary inspection system considered to be equivalent to the Brazilian system must request the eligibility of the establishments by means of a computerized system made available in MAPA's website.

Article 23. DIPOA is authorized to update, ratify and disclose the list of foreign countries authorized to export to Brazil by cross-checking the information about the foreign establishments that are already eligible, and the history of imports of animal products.

Sole paragraph. DIPOA is authorized to exclude the foreign establishments that do not trade with Brazil for a 5-year period.

Art. 24. This Normative Instruction shall be in force as of the date of its publication.

JORGE CAETANO JUNIOR - Deputy